In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-203V

Filed: May 14, 2019

GABRIEL GALINDO, *Legal Representative on behalf of The Estate of* KYARA GALINDO,	*	UNPUBLISHED
Petitioner,	*	Dismissal; Ruling on the Record; Human Papillomavirus ("HPV") Vaccine; Glioblastoma; Significant Aggravation
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Meredith Troberman, Esq., Carroll Troberman, PLLC, Austin, TX, for petitioner.
Mallori Openchowski, Esq., U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

Roth, Special Master:

On February 10, 2016, Kyara Galindo ("Ms. Galindo") filed a petition for compensation pursuant to the National Vaccine Injury Compensation Program,[2] alleging that she received human papillomavirus ("HPV") vaccinations on June 1, 2011 and August 1, 2011, and thereafter suffered from glioblastoma which was caused by the HPV vaccine. *See* Petition ("Pet."), ECF No. 1. Following Ms. Galindo's death, her father Gabriel Galindo, was substituted for petitioner as the legal representative of her estate. *See* ECF Nos. 10, 12. The petition was later amended, in order to cure timeliness problems with the initial Petition, to allege that Ms. Galindo received an HPV

[1] Although this Decision has been formally designated "unpublished," it will nevertheless be posted on the Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). **This means the Decision will be available to anyone with access to the internet.** However, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id.*

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

vaccination on January 21, 2013, which significantly aggravated her pre-existing glioblastoma. *See* Amended Petition ("Am. Pet."), ECF No. 11.

Petitioner has filed Motions for Ruling on the Record. The undersigned finds that petitioner has failed to carry his burden of showing that the HPV vaccination caused or significantly aggravated Ms. Galindo's glioblastoma. The petition is accordingly dismissed.

I. Background

A. Procedural History

The petition was filed on February 10, 2016. ECF No. 1. The petition stated that Kyara Galindo received HPV vaccinations on June 1, 2011 and August 1, 2011 before being diagnosed with glioblastoma on October 2, 2011. Pet. at ¶¶3, 5. "After a course of treatment, [Ms. Galindo] was determined to be cancer free." *Id*. at ¶6. The petition further stated, "In 2015, [Ms. Galindo] received another [HPV] vaccination and within two months was diagnosed with Glioblastoma." *Id*. at ¶7. The petition alleged that Ms. Galindo's glioblastoma was caused-in-fact by the HPV vaccinations she received on June 1, 2011 and August 1, 2011. *Id*. at ¶9. The petition further alleged that Ms. Galindo's relapse was caused by the third HPV vaccination she received in 2015.[3] *Id*. at ¶10.

This matter was assigned to me on February 12, 2016. ECF No. 4. That same day, I issued an initial order. ECF No. 5. The initial status conference was held on May 18, 2016. Scheduling Order at 1, ECF No. 8. At that time, petitioner was represented by Omar Rosales, Esq. *Id*. During the conference, I noted that the allegations contained in the petition were for vaccinations received on June 1, 2011 and August 1, 2011, which would place the claim outside of the statute of limitations.[4] *Id*. However, I also noted that the petition stated that Ms. Galindo had a relapse of glioblastoma following her third HPV vaccination. *Id*. I also suggested to Mr. Rosales that the petition be amended to allege a significant aggravation claim based on the third HPV vaccination. *Id*. Mr. Rosales agreed to file an amended petition. *Id*.

A number of filings occurred on July 6, 2016. Petitioner incorrectly filed his amended petition as an "Amended Complaint." *See* ECF No. 9. Petitioner then filed a Motion to Strike the Amended Complaint, which was granted, and an Amended Petition was filed. *See* ECF Nos. 11, 13; Non-PDF Order, dated July 6, 2016. In his Amended Petition, petitioner alleged that Ms. Galindo's glioblastoma was caused-in-fact by the third HPV vaccination, which she received on January 21, 2013. Am. Pet. at ¶9. "Ms. Galindo's cancer was a result of the [HPV] vaccination. Although Ms. Galindo was told she was cancer-free in 2012, Galindo (sic) had a subsequent relapse after receiving a third [HPV] vaccination on January 21, 2013." *Id*. at ¶10. Petitioner

[3] Ms. Galindo received the third HPV vaccine on January 21, 2013. Pet. Ex. 7 at 4.

[4] *See* 42 U.S.C. § 300aa-16(a)(2), providing that petitions for vaccine-related injuries occurring as the result of vaccines administered after October 1, 1988 must be filed within 36 months of "the date of the first symptom or manifestation of onset or of the significant aggravation of such injury…."

alleged, in the alternative, that the third HPV vaccination significantly aggravated Ms. Galindo's preexisting glioblastoma.[5] *Id.* at ¶11.

That same day, petitioner filed a Motion to Amend the Caption to reflect that Ms. Galindo had passed and her father, Gabriel Galindo, would be substituting in as the legal representative of her estate. Motion at 1, ECF No. 10. This motion was granted. *See* ECF No. 12. Additionally, petitioner incorrectly filed Petitioner's Exhibits ("Pet. Ex.") 1-5 and then filed a Motion to Strike these exhibits, which was granted. *See* ECF Nos. 14, 15; Non-PDF Order, dated July 6, 2016.

The next day, July 7, 2016, petitioner filed Ms. Galindo's birth certificate as well as various medical records. *See* Pet. Ex. 1-5, ECF No. 16; Pet. Ex. 6-7, ECF No. 17; Pet. Ex. 10, ECF No. 18. Petitioner filed an affidavit from Gabriel Galindo, affirming that Kyara Galindo received HPV vaccinations on June 1, 2011, August 2, 2011, and January 21, 2013. Pet. Ex. 9 at 1; ECF No. 17. Petitioner also filed an expert report and CV from Dr. Mark Levin along with a case report of a connection between the HPV vaccine and cerebral vasculitis.[6] Pet. Ex. 8, ECF No. 17; ECF No. 19.[7]

During a status conference held on August 11, 2016, Dr. Levin's report was discussed, along with the necessity to satisfy the requirements set forth in *Althen*. Scheduling Order at 1, ECF No. 21. Counsel was informed that, in addition to satisfying *Althen*, petitioner's expert witness must demonstrate that the recurrence of Ms. Galindo's glioblastoma was caused by the final HPV vaccine she received on January 21, 2013. *Id.* I discussed with Mr. Rosales that the medical records that were filed indicated that Ms. Galindo's recurrence of glioblastoma was in June of 2015, 16 months after she received the third HPV vaccine.[8] *Id.* Mr. Rosales advised that Ms. Galindo began experiencing symptoms related to her recurrence of glioblastoma in September of 2013, approximately 8 months after her third HPV vaccination. *Id.* I discussed with Mr. Rosales that the medical records did not support a recurrence in September of 2013. *Id.* I further discussed with Mr. Rosales that there were significant gaps in the medical records. *Id.* Mr. Rosales agreed to provide medical records of all treatment following Ms. Galindo's first glioblastoma diagnosis as well as all medical records of any treatment from the fall of 2011 until her death. *Id.* Mr. Rosales was advised to have his expert review the additional medical records when drafting his supplemental expert report. *Id.* at 2. Finally, Mr. Rosales was directed to contact the Clerk's Office if he needed assistance in filing documents in accordance with the Vaccine Rules. *Id.* An order issued for the filing of all outstanding medical records by October 12, 2016. *Id.*

[5] Ms. Galindo had a recurrence of glioblastoma in June of 2015, 28 months after her third HPV vaccination. Pet. Ex. 11 at 4, 47, 86.

[6] Lucija Tomljenovic & Christopher A. Shaw, *Death after Quadrivalent Human Papillomavirus (HPV) Vaccination: Causal or Coincidental?*, 12 PHARMACEUT REG AFFAIRS 1: 1-11 (2012).

[7] Dr. Levin's first expert report and CV, located at ECF No. 19, were not filed with exhibit numbers.

[8] This order stated that, according to the medical records, there was a 16-month gap between Ms. Galindo's third HPV vaccination on January 21, 2013, and her recurrence of glioblastoma in June of 2015. This is factually incorrect; there was a 28-month gap between January of 2013 and June of 2015.

On October 24, 2016, petitioner filed a "Notice," which was out of time, stating that the medical records filed to date constituted the entire patient records, and there were no additional records to submit. Notice at 1, ECF No. 24. Petitioner requested a deadline to submit his supplemental expert report. *Id*. An Order was issued for petitioner to file a supplemental expert report which satisfied the requirements of both *Althen* and *Loving* by December 27, 2016. Scheduling Order at 2, ECF No. 24.

On December 27, 2016, petitioner filed a supplemental expert report from Dr. Mark Levin. Pet. Ex. 12, ECF No. 26. Respondent was ordered to file an expert report by March 28, 2017. Non-PDF order, dated Dec. 28, 2016. On March 24, 2017, respondent filed an unopposed Motion for Extension of Time until May 12, 2017, to file an expert report. ECF No. 27. This Motion was granted. Non-PDF Order, dated Mar. 24, 2017. Respondent filed an expert report from Dr. Joan Gill on May 9, 2017. Resp. Ex. A-B. A status conference was scheduled for June 28, 2017. Non-PDF Order, dated May 16, 2017.

On June 9, 2017, petitioner filed an "unopposed" Motion for Ruling on the Record ("Mot. Ruling"). ECF No. 31. Petitioner submitted that Ms. Galindo was asymptomatic prior to receiving an HPV vaccination on June 2, 2011 but developed glioblastoma "shortly thereafter" on or about September 12, 2011. Mot. Ruling at 1. Petitioner further submitted that Ms. Galindo's glioblastoma recurred after the "second round" of HPV vaccinations, which occurred on January 21, 2013.[9] *Id*. at 2. Petitioner cited to Dr. Levin's recitation of the *Althen* criteria as evidence of causation. *Id*. at 1, citing Pet. Ex. 12 at 2-3 ("In my opinion, there is a medical theory that causally connects the vaccination and the injury; there is a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and there is a proximate temporal relationship between vaccination and injury").

Respondent filed a response ("Ruling Resp.") on June 26, 2017, requesting that petitioner's claim be dismissed. ECF No. 32. Respondent submitted, "Petitioner rests his Motion solely on Dr. Levin's reports," which suggested that the HPV vaccine acted as a "promotor" that accelerated the "growth and virulence" of Ms. Galindo's glioblastoma. Ruling Resp. at 6, 10. Respondent argued that Dr. Levin's reports did not meet the standards articulated by *Althen* or *Loving*. *Id*. at 9, 11.

During a status conference held on June 28, 2017, it was noted that petitioner's supplemental expert report quoted the *Althen* criteria but did not address the criteria substantively. Scheduling Order at 1, ECF No. 33. It was further noted that the report referenced literature which had not been filed with the Court. *Id*. Mr. Rosales was reminded of the necessity of satisfying the *Althen* criteria in order to demonstrate entitlement to compensation. *Id*. It was suggested that petitioner move to strike his Motion for a Ruling on the Record and seek to develop the record further. *Id*. Mr. Rosales agreed; he requested 30 days to file a status report advising how petitioner would like to proceed, and 90 days to file a report from petitioner's expert which addressed the

[9] The content of the Motion was factually incorrect. The medical records that were filed in this matter state that Ms. Galindo received her first HPV vaccination on June 1, 2011, a second HPV vaccination on August 1, 2011, and a third HPV vaccination on January 21, 2013, and was diagnosed with glioblastoma in October of 2011. *See* Pet. Ex. 7 at 3-4.

Althen criteria.[10] *Id*. Petitioner was also ordered to file Ms. Galindo's death certificate and proof that Ms. Galindo's father had been appointed as the legal representative of her estate. *Id*. at 2.

Petitioner filed Ms. Galindo's death certificate on July 6, 2017. Pet. Ex. 11,[11] ECF No. 34. Petitioner filed petitioner's application for probate of Ms. Galindo's will and issuance of letters testamentary on July 20, 2017. Pet. Ex. 12, ECF No. 35. On July 25, 2017, petitioner filed letters testamentary showing Gabriel Galindo as executor of Ms. Galindo's estate. Pet. Ex. 13, ECF No. 36. Additionally, petitioner filed a second supplemental report from Dr. Levin along with several articles of medical literature.[12] Pet. Ex. 14-15, ECF No. 37. Petitioner also filed a status report ("Pet. S.R.") requesting "that the Court issue a ruling on the record, based upon the evidence submitted, the three expert reports, the theory of causation, the lack of risk factors, and the substantial reference materials included by Petitioner." Pet. S.R. at 1, ECF No. 38.

In response to this request, an Order was issued on July 26, 2017, advising that a Ruling on the Record required a detailed evaluation of the medical records and expert reports and would be made publicly available on the Court's website. Scheduling Order at 1, ECF No. 39. Petitioner was offered the opportunity for a hearing to explore the bases of Dr. Levin's opinion. *Id*. Petitioner was ordered to file an affidavit affirming that he understood the foregoing. *Id*. Additionally, the Order noted that petitioner's theory of causation relied on the presence of HPV-16L particles in the brain tissue. *Id*. at 1-2. Petitioner was ordered to file either Ms. Galindo's autopsy report or a status report indicating that no autopsy was performed. *Id*. at 2. Respondent was ordered to file a supplemental expert report; he did so on October 19, 2017. *Id*.; *see also* Resp. Ex. C, ECF No. 42.

On July 27, 2017, petitioner filed an affidavit waiving his opportunity for a hearing. ECF No. 40. Petitioner also filed a status report ("Pet. S.R") advising that no autopsy was done on Ms. Galindo and reiterating his request that the Court issue a Ruling on the Record. Pet. S.R. at 1, ECF No. 41.

On October 23, 2017, petitioner filed a second "unopposed" Motion for Ruling on the Record ("2nd Mot. Ruling"). ECF No. 43. Petitioner again wrote that Ms. Galindo was asymptomatic prior to receiving an HPV vaccination on June 2, 2011 but developed glioblastoma on or around September 12, 2011. *Id*. at 1. Similarly, petitioner repeated that Ms. Galindo's glioblastoma recurred after the "second round" of HPV vaccinations she received on January 21, 2013. *Id*. at 2. Petitioner submitted that "immune cells and vaccine-derived immune complexes can cross the blood-brain barrier and trigger an [sic] neurodestructive autoimmune process. HPV-16L1 VLPs can invade the CNS through a macrophange-dependent [sic] Trojan horse mechanism and deposit on the walls of cerebral blood vessels." *Id*. In support of this theory, petitioner pointed out that Ms. Galindo did not have any risk factors which would predispose her to glioblastoma, nor did she "fit the statistical profile of the common [glioblastoma] patient." *Id*.

[10] This order only instructed petitioner to address the *Althen* criteria; the *Loving* criteria were inadvertently omitted.

[11] Petitioner had already filed medical records as "Pet. Ex. 11." *See* ECF No. 20.

[12] Petitioner's articles of medical literature and Dr. Levin's report were filed together as one exhibit, Pet. Ex. 14.

On November 6, 2017, respondent filed a response ("2nd Ruling Resp.") to petitioner's submission, requesting that petitioner's claim be denied, and his case be dismissed. 2nd Ruling Resp. at 12, ECF No. 44. Respondent again submitted that petitioner had not provided preponderant evidence of actual causation under *Althen* or of significant aggravation under *Loving*. *Id*. at 8-10. Respondent proffered the opinion of his expert, Dr. Joan Gill, that Ms. Galindo's "recurrence occurred in the natural history of her glioblastoma, an "inevitably progressive" disease." *Id*. at 11, citing Resp. Ex. A at 3.

On December 21, 2017, the Court of Federal Claims Standing Panel on Attorney Discipline issued an order stating that Mr. Rosales had been suspended from the practice of law in the Western District of Texas. Order at 1, ECF No. 45. The Order further stated that Mr. Rosales had filed an appeal before the Fifth Circuit Court of Appeals, which was awaiting disposition. *Id*. The Standing Panel was waiting for the appeal to conclude before requiring Mr. Rosales to respond to an Order to Show Cause that had been issued by the Standing Panel. *Id*. The Clerk of Court was directed to reject filings from Mr. Rosales in all of the vaccine cases in which he was the attorney of record. *Id*. at 2.

In light of the order issued by the Standing Panel, an order ("1st Stay") was issued on January 23, 2018, suspending these proceedings for up to 130 days or pending further orders from the Standing Panel. 1st Stay at 1, ECF No. 46.

On March 27, 2018, petitioner filed a petition for a Writ of Mandamus in the Federal Circuit. *See* Notice at 4, ECF No. 51.

On April 18, 2018, the Standing Panel on Attorney Discipline issued an order stating that the U.S. Court of Appeals for the Fifth Circuit had affirmed the Western District of Texas's decision to suspend Mr. Rosales from practice for three years. Order at 1, ECF No. 50. Mr. Rosales was ordered to respond to the Panel's Show Cause Order by May 14, 2018. *Id*.

On May 22, 2018, the U.S. Court of Appeals for the Federal Circuit issued an order denying petitioner's Motion for a Writ of Mandamus. Notice at 1, ECF No. 51. The Federal Circuit rejected petitioner's claim of unreasonable delay in reaching a decision in this matter. *Id*. at 1-2.

On June 4, 2018, an order ("2nd Stay") was issued continuing the stay previously ordered but not to exceed an additional 50 days, in light of Mr. Rosales' temporary suspension from practice in the U.S. Court of Federal Claims. ECF No. 52.

On July 27, 2018, the Standing Panel on Attorney Discipline issued an order suspending Mr. Rosales from practicing in the U.S. Court of Federal Claims for three years. Order at 3, ECF No. 53. The Order required the Clerk of Court to remove Mr. Rosales as attorney of record in this matter. *Id*. Petitioner was thereby rendered *pro se*.

On August 2, 2018, an order was issued advising petitioner that Mr. Rosales had been suspended from practice in the U.S. Court of Federal Claims. Order at 1, ECF No. 54. I encouraged petitioner to reach out to attorneys with experience practicing in the Vaccine Program to retain new counsel and enclosed a list of such attorneys. *Id*. Petitioner was ordered to contact the Court

by September 4, 2018, advising of his progress in retaining counsel. *Id*. Petitioner did not respond to that order; I issued another order on September 11, 2018, encouraging petitioner to contact my chambers to schedule a status conference to discuss his claim. Order at 1, ECF No. 55. On September 12, 2018, a letter was received from petitioner stating that he had been in contact with an attorney and had a meeting with the attorney scheduled for the following week. Letter at 1, ECF No. 56. Having not heard from petitioner for several weeks, I issued an order on October 9, 2018, again encouraging petitioner to contact an attorney with experience in the Vaccine Program. Order at 1, ECF No. 57. Petitioner was ordered to contact my chambers by October 23, 2018, to schedule a status conference. *Id*.

On October 29, 2018, a Motion to Substitute Meredith Troberman in place of Omar Rosales as counsel of record was incorrectly filed. ECF No. 58. A status conference with Ms. Troberman was scheduled for October 31, 2018. Status Conference Order at 1, ECF No. 59. During the conference, I informed Ms. Troberman that because petitioner was *pro se*, the Motion for Substitution needed to be filed in paper form along with an affidavit from petitioner acknowledging his hiring of counsel. Scheduling Order at 1, ECF No. 60. I provided Ms. Troberman with a history of this matter, pointing out that the medical records were incomplete, and that petitioner's expert, Dr. Levin, based his reports on incomplete records and an inaccurate timeline of events. *Id*. at 2. I suggested that petitioner consider withdrawing both motions for ruling on the record in order to further develop the record. *Id*. Respondent was ordered to file a status report by November 30, 2018, advising whether respondent was amenable to petitioner's new counsel withdrawing the pending motions for ruling on the record. *Id*. Ms. Troberman was ordered to file a status report by January 29, 2019, advising that she had reviewed the record and indicating whether the record was complete. *Id*.

On November 30, 2018, respondent filed a status report ("Resp. S.R.") deferring to me as to whether a future request from petitioner to withdraw the pending motions for ruling on the record should be granted. Resp. S.R. at 1, ECF No. 61.

The Motion for Substitution of Counsel was not filed. On December 17, 2018, I issued an order providing petitioner with instructions on how to properly file a Motion for Substitution of Attorney, and set a deadline of January 4, 2019, for petitioner to properly file a Motion to Substitute Ms. Troberman as his attorney of record. Scheduling Order at 1-2, ECF No. 62.

On January 15, 2019, petitioner properly filed a consented Motion to Substitute Attorney Meredith Troberman as counsel of record. ECF No. 63.

On January 29, 2019, petitioner filed a status report[13] ("Pet. S.R.") stating, "While we understand the Special Master's concerns regarding the medical records and the timeline associated with the onset of symptoms, Petitioner's evidence is now complete. There are no additional medical records that Petitioner intends to supplement for the record." Pet. S.R. at 1, ECF No. 66. Petitioner repeated his request for a ruling on the record, "based upon the evidence

[13] On January 29, 2019, petitioner filed two identical status reports in error, located at ECF Nos. 65 and 66. Petitioner later filed a Motion to Strike the first status report, which was granted. *See* Motion, ECF No. 67; Order, ECF No. 68.

submitted: three expert reports; the theory of causation; the lack of risk factors; and the substantial reference materials included by the Petition." *Id.*

Succinctly, the record as it stands is incomplete. Many of petitioner's medical records were not filed, particularly complete records of her oncology, surgery, chemotherapy, and radiation treatments. Additionally, there are gaps in the records which are unaccounted for. Furthermore, many of the articles cited to and relied upon by Dr. Levin in his report was never filed. Finally, the timeline Dr. Levin relied upon as a basis of his decision is inaccurate and inconsistent with the medical records that were filed into the record. Despite being offered several opportunities to develop the record, file missing medical records and literature, and submit an expert report from Dr. Levin based on the correct timeline of events consistent with the medical records, petitioner insisted that I rule on the record as it was filed.

This matter is therefore ripe for decision.

B. Petitioner's Health Prior to the January 21, 2013 HPV Vaccination

The medical records as filed show the following:

Ms. Galindo was born on December 26, 1995. Pet. Ex. 1 at 1. She experienced normal childhood illness like sore throats and sinus infections but was otherwise healthy.[14] *See generally* Pet. Ex. 10.

On June 1, 2011, Ms. Galindo presented to Mid-Texas Health Care Association ("Mid-Texas") for a well-child visit. Pet. Ex. 2 at 1. She had a normal examination. *Id*. at 3. She was noted to have acne and was prescribed Differin.[15] *Id*. at 3. She was administered her first HPV vaccine. *Id*. at 4.

Ms. Galindo received a second HPV vaccination on August 1, 2011.[16] Pet. Ex. 7 at 3.

On September 12, 2011, Ms. Galindo presented to Mid-Texas complaining of acute sinusitis for the past week with headache, nasal congestion, nausea, and vomiting. Pet. Ex. 4 at 1. The assessment was "TMJ[17] syndrome." *Id.* She was educated on TMJ syndrome and prescribed indomethacin.[18] *Id*. at 2.

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[14] The records provided only encompass Ms. Galindo's early childhood. Petitioner did not provide medical records for the three years prior to Ms. Galindo's first HPV vaccine on June 1, 2011.

[15] Differin is a brand name of adapalene, a topical medication used to treat acne. *Adapalene*, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 25 (32d ed. 2012) [hereinafter DORLAND'S]; *Differin*, DORLAND'S at 516.

[16] There are no medical records documenting a visit to Mid-Texas for this vaccination.

[17] "TMJ" stands for "temporomandibular joint." *TMJ*, DORLAND'S at 1932.

[18] Indomethacin is a nonsteroidal anti-inflammatory drug used to treat a variety of conditions, including vascular headaches. *Indomethacin*, DORLAND'S at 932.

Ms. Galindo returned to Mid-Texas three days later, on September 15, 2011. She reported that the indomethacin did not help her symptoms, and she continued to suffer from headache, nausea, TMJ pain, and vomiting. Pet. Ex. 4 at 3. The assessment was "classic migraine." *Id*. She was given samples of Treximet[19] and prescribed promethazine.[20] *Id*. at 4. She was instructed to schedule a follow-up appointment in five days. *Id*. If the migraine medicines did not help, she would be sent for a head CT.[21] *Id*.

Four days later, on September 19, 2011, Ms. Galindo presented to Mid-Texas for a second opinion. Pet. Ex. 4 at 5. She was still complaining of headaches, nausea, and vomiting. *Id*. The assessment was headache, with best results from Bupap;[22] migraine was suspected since the pain was post-orbital on the right side. *Id*. She was prescribed amoxicillin and prednisone. *Id*. at 6.

On October 2, 2011, Ms. Galindo presented to Hill Country Memorial Hospital for a head CT. Pet. Ex. 5 at 2. The CT showed two masses present in the right hemisphere involving the frontoparietal region with significant mass effect and right-to-left midline shift. *Id*. The differential diagnosis included neoplasm, such as multifocal glioma, metastatic disease, or infection. *Id*. The assessment was "unspecified brain tumor." *Id*. at 1. An MRI with contrast was recommended.[23] *Id*. at 2.

Ms. Galindo underwent a craniotomy on October 3, 2011. Pet. Ex. 11 at 48. She did well for one month and then developed a cystic fluid collection which required draining in November. *Id*. She had radiation treatments from late November 2011 through early January 2012, with concomitant temozolomide.[24] *Id*.[25]

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[19] Treximet is a combination of naproxen sodium and sumatriptan used to treat migraines. *Physicians' Desk Reference* 1352, 1354 (66th ed. 2012), [hereinafter "PDR"].

[20] Promethazine is an antihistamine used to treat or prevent nausea and vomiting. *Promethazine hydrochloride – Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/Promethazine-Hydrochloride-Tablets-promethazine-hydrochloride-1288 (last visited Mar. 25, 2019).

[21] Not having the benefit of any medical records for the years prior to Ms. Galindo's June 1, 2011 physical makes it difficult to ascertain why her complaints of headache were handled in this manner and suggests that she may have had a history of headaches or migraines in the past.

[22] Bupap is a brand name for a combination of acetaminophen and butalbital, a barbiturate; it is used to treat tension headaches. *Acetaminophen/butalbital – Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/Bupap-acetaminophen-butalbital-3256 (last visited Apr. 18, 2019).

[23] There is no record of this MRI.

[24] Temozolomide is a chemotherapy drug used to treat patients with newly-diagnosed glioblastoma multiforme in conjunction with radiation and then as a maintenance treatment. *PDR* at 2062-63. The most common side effects are alopecia, nausea, vomiting, anorexia, headache, and constipation. *Id*. at 2065.

[25] Petitioner did not file records documenting the craniotomy in October, the procedure in November, the radiation treatments occurring from November of 2011 through January of 2012 or any medical visits with any medical providers. This information was obtained from the history noted in an oncology visit on April 7, 2016. *See* Pet. Ex. 11 at 48.

On December 26, 2011, Ms. Galindo presented to Hill Country Emergency Department. According to the intake note, Ms. Galindo's boyfriend reported that 10 minutes prior to arrival, Ms. Galindo was sitting in a chair and started having jerking in her left eye, face, and left arm for approximately five minutes. Pet. Ex. 5 at 9. She was administered 1 mg of clonazepam. *Id*. at 9. The primary impression was possible seizure secondary to glioblastoma. *Id*. at 11. The history taken noted that Ms. Galindo had a partial tumor removal on October 3, 2011, and a cyst removed from her brain on November 7, 2011. *Id*. at 10. She was taking 0.5 mg of dexamethasone[26] daily. *Id*. at 9. A head CT was ordered; it showed "A right frontoparietal nonenhancing cystic area…present in the areas of previous mass effect.... A tiny amount of dural enhancement at the superior margin of the cystic area is present…. Except for the thin rim of enhancement, abnormalities to suggest an enhancing neoplasm are not apparent.…Additional lesions elsewhere are not identified." *Id*. at 11, 15. She was discharged home with instructions to follow up with her oncologist, Dr. Quezada, "tomorrow." *Id*. at 5, 14.

The next record filed is for a medical visit on March 8, 2012. Ms. Galindo presented to Mid-Texas for a CBC and comprehensive metabolic panel. Pet. Ex. 5 at 1, 17-18. She was noted to have an unspecified brain tumor. *Id*. Repeat bloodwork was conducted on March 26, 2012. *Id*. at 19; Pet. Ex. 10 at 99.

On March 29, 2012, Ms. Galindo presented to Mid-Texas for a well-child check. Pet. Ex. 10 at 100. Dr. Haug noted that Ms. Galindo was currently undergoing chemotherapy[27] for glioblastoma but was back in school. *Id*. She reported fatigue, dry throat due to medications, and nausea and vomiting following chemotherapy. *Id*. at 100-01. Her current medications included cyclobenzaprine,[28] promethazine, indomethacin, and Differin gel. *Id*. at 102. She was prescribed Remeron,[29] a vitamin, and Epiduo gel.[30] *Id*. at 103.

From March through of September of 2012, Ms. Galindo continued to present to Mid-Texas regularly for bloodwork.[31] *See* Pet. Ex. 5 at 21-23; Pet. Ex. 10 at 62, 65-66, 69-71, 105-06.

On September 12, 2012, Ms. Galindo presented to Hill Country Emergency Department for possible port displacement. Pet. Ex. 10 at 74. She was noted to have a port for chemotherapy on the left side of her chest.[32] *Id*. Radiography showed that the port was in place, the lungs were

[26] Dexamethasone is a steroid used an antiemetic (to prevent or alleviate nausea and vomiting) in cancer chemotherapy. *Dexamethasone*, DORLAND'S at 504; *antiemetic*, DORLAND'S at 103.

[27] Records documenting Ms. Galindo's chemotherapy treatment were not filed.

[28] Cyclobenzaprine is a muscle relaxer used to treat muscle spasms. *Cyclobenzaprine*, DORLAND'S at 455.

[29] Remeron is the brand name for mirtazapine, an antidepressant. *Remeron*, DORLAND'S at 1623; *mirtazapine*, DORLAND'S at 1169.

[30] Epiduo is a brand name for adapalene, a topical drug used to treat acne. *Adapalene/benzoyl peroxide – Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/Epiduo-adapalene-benzoyl-peroxide-2490 (last visited Mar. 25, 2019).

[31] Petitioner did not file any records of primary care office visits to correspond with this bloodwork.

[32] No records of when the port was implanted were filed.

clear, and there was no evidence of pneumothorax. *Id*. at 77-78. No treatment was rendered; Ms. Galindo was instructed to follow-up with her primary care provider. *Id*. at 77.

Ms. Galindo returned to Mid-Texas multiple times in October and November of 2012 for repeat bloodwork. *See* Pet. Ex. 10 at 79-81. She continued with Temodar,[33] irinotecan,[34] and bevacizumab[35] through December 2012.[36] Pet. Ex. 11 at 47.

C. Petitioner's Health Following the January 21, 2013 HPV Vaccination

On January 21, 2013, Ms. Galindo presented to Mid-Texas for a well-child exam. Pet. Ex. 7 at 1. She was noted to have a history of glioblastoma, with craniotomies on October 3 and November 1, 2011, followed by radiation and chemotherapy. *Id*. at 2. She had two ports placed.[37] *Id*. Her current problems were listed as acne and unspecified brain tumor. *Id*. at 3. Upon exam, she was noted to be thin with alopecia.[38] *Id*. at 3. She received a third HPV vaccine and an intranasal flu vaccine. *Id*. at 4.

The next medical record filed is eight months later, on August 5, 2013. Ms. Galindo presented to Mid-Texas with vaginal irritation and white vaginal discharge present for one to two days. Pet. Ex. 6 at 1. The assessment was "[v]aginal discharge, unspecified probably from stress and wet bathing suits." *Id*. at 1. She was prescribed fluconazole[39] and metronidazole.[40] *Id*. at 1-2.

The next medical record filed was for November 1, 2013. Ms. Galindo presented to Mid-Texas with a sore throat, fever, nausea, and "swollen glands." Pet. Ex. 6 at 3. She had tried ibuprofen without relief. *Id*. Upon exam, she had erythema present on her gums and her lymph nodes were noted to be firm. *Id*. at 3. She was diagnosed with acute pharyngitis and prescribed amoxicillin. *Id*. at 3-4.

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[33] Temodar is the brand name for temozolomide. *PDR* at 2062.

[34] Irinotecan is a chemotherapeutic drug typically used to treat metastatic colorectal cancer. It is used in combination with bevacizumab to treat recurrent or relapse glioblastoma. *Irinotecan hydrochloride – Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/Camptosar-irinotecan-hydrochloride-1017 (last visited Mar. 25, 2019).

[35] Bevacizumab is a chemotherapeutic drug used to treat several types of cancer, including recurrent glioblastoma. *Bevacizumab – Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/Avastin-bevacizumab-2073.4428 (last visited Mar. 25, 2019).

[36] No records documenting Ms. Galindo's office visits with her primary care provider or oncologist during this period of time were filed. A later record documenting treatment on April 7, 2016, states that Ms. Galindo "continued with Temodar, Irinotecan, and bevacizumab through December 2012." Pet. Ex. 11 at 47.

[37] There were no records filed documenting the port placements.

[38] Alopecia is lack or loss of hair from skin areas where it is normally present. *Alopecia*, DORLAND'S at 53.

[39] Fluconazole is an antifungal drug used to treat candidiasis. *Fluconazole*, DORLAND'S at 719.

[40] Metronidazole is an antibiotic used to treat bacterial vaginosis. *Metronidazole*, DORLAND'S at 1155.

On December 5, 2013, Ms. Galindo presented to Mid-Texas with chest congestion, nocturnal cough, frontal facial pressure, headache, nasal congestion, post-nasal drip and rhinorrhea ongoing for three days. Pet. Ex. 10 at 116. She was diagnosed with acute sinusitis and prescribed doxycycline,[41] guaifenesin,[42] and Cheratussin.[43] *Id*. at 117. She was administered an intranasal flu vaccine. *Id*.

On January 8, 2014, Ms. Galindo presented to Mid-Texas with congestion ongoing for one to two days. She had front and maxillary facial pressure, nasal congestion and post-nasal drip. Pet. Ex. 10 at 118. She also complained of fatigue and purulent left eye drainage. *Id*. She was diagnosed with allergic sinusitis and prescribed prednisone, fexofenadine,[44] and Nasonex. *Id*. at 119.

On February 14, 2014, Ms. Galindo presented to Mid-Texas for a well child check. Pet. Ex. 10 at 120. She was noted to have malignant glioblastoma with no apparent recurrence or problems from chemotherapy. *Id*. at 123.

On March 24, 2014, Ms. Galindo presented to Mid-Texas for a well child check. Pet. Ex. 10 at 125. Her current medications included TriNessa[45] and Nasonex. *Id*. She received a meningococcal conjugate vaccination. *Id*.

On March 25, 2014, Ms. Galindo presented to Mid-Texas for nausea and vomiting for the past 12 hours. Pet. Ex. 10 at 126. She also complained of chills, fever, and dizziness. *Id*. Upon exam, she had mild periumbilical tenderness. *Id*. The impression was acute appendicitis. *Id*. at 127. She was prescribed ondansetron HCl[46] and indomethacin. *Id*.

Ms. Galindo returned to Mid-Texas on March 27, 2014, for a follow-up of generalized abdominal pain. Pet. Ex. 10 at 128. She reported that her symptoms improved following indomethacin and ondansetron. *Id*. She reported dizziness upon positional change. *Id*. No treatment was recommended. *Id*.

No records were filed reflecting medical treatment occurring from March 27, 2014, until February 18, 2015, when Ms. Galindo presented to Mid-Texas with abdominal pain that began

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[41] Doxycycline is a broad-spectrum antibiotic. *Doxycycline*, DORLAND'S at 565.

[42] Guaifenesin is an expectorant, a drug that promotes the ejection of mucus from lungs, by reducing mucus viscosity. *Guaifenesin*, DORLAND'S at 809; *expectorant*, DORLAND'S at 661.

[43] Cheratussin is the brand name for the combination of guaifenesin and codeine in a syrup preparation. It is used to treat cough and cold. *Codeine phosphate/guaifenesin – Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/Cheratussin-AC-codeine-phosphate-guaifenesin-1653.59 (last visited Mar. 25, 2019).

[44] Fexofenadine is an antihistamine used to treat hay fever. *Fexofenadine*, DORLAND'S at 695.

[45] TriNessa is the brand name for a combination of ethinyl estradiol and norgestimate, an oral contraceptive. *Ethinyl estradiol/norgestimate – Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/MonoNessa-TriNessa-ethinyl-estradiol-norgestimate-3380 (last visited Mar. 25, 2019).

[46] Ondansetron HCl, or ondansetron hydrochloride, is a drug used to prevent nausea and vomiting occurring in conjunction with cancer chemotherapy. *Ondansetron hydrochloride*, DORLAND'S at 1321.

four days before. Pet. Ex. 10 at 129. She reported that on Monday evening (2 days before) she went to the emergency room,[47] where she was diagnosed with bacterial vaginosis and prescribed metronidazole. *Id.* She reported abdominal bloating, diarrhea, and pain which she described as "twisting her intestines." *Id*. The pain was aggravated by meals and relieved with a heating pad. *Id*. She was suspected of having an ovarian cyst and was prescribed indomethacin. *Id*. at 129-30.

Ms. Galindo apparently suffered from a recurrence of or progression of glioblastoma diagnosed on June 30, 2015.[48] Pet. Ex. 11 at 4, 47, 86. No records were filed reflecting medical treatment occurring from February 18, 2015, until January 6, 2016.

The following history was provided in records filed from visits in 2016. On January 6, 2016, Ms. Galindo presented to Elizabeth Diaz, a physician's assistant working with Ms. Galindo's oncologist, Dr. Brenner, for "ongoing treatment on Phase 2 trial of TH-302 and Avastin"[49] which she was noted to have begun on September 10, 2015. Pet. Ex. 11 at 92. Two weeks prior, she had developed an abscess in the right inguinal region which was treated with incision and drainage by her primary care provider and resolved following antibiotics.[50] *Id.* She had developed left sided facial droop at some point prior that was slightly worse with occasional drooling, and she could not wink on one side. *Id*. She also reported mild dysarthria.[51] *Id*. Upon exam, she was noted to have left cranial nerve VII palsy, mild dysmetria[52] on the left side, and hyperpigmentation on her hands. *Id*. at 95. She was taking Keppra[53] for focal seizures.[54] *Id*. at 96. It was recommended that she continue with TH-302 plus Avastin, Silvadene cream,[55] and triamcinolone cream.[56] *Id*. She was to decrease IV Ativan[57] to 0.5 mg and return for a brain MRI as scheduled. *Id*.

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[47] Records of Ms. Galindo's emergency room visit on February 16, 2015, were not filed.

[48] Petitioner did not file medical records directly documenting Ms. Galindo's recurrence; rather, this information has been gleaned from her medical history as summarized by her doctors at subsequent visits.

[49] Avastin is the brand name for bevacizumab. *Bevacizumab – Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/Avastin-bevacizumab-2073.4428 (last visited Mar. 25, 2019).

[50] Records of this primary care visit were not filed.

[51] Dysarthria is a speech disorder consisting of imperfect articulation due to loss of muscular control after damage to the central or peripheral nervous system. *Dysarthria*, DORLAND'S at 575.

[52] Dysmetria is a lack of coordination caused by an inability to properly estimate distance required for a muscle movement. *Dysmetria*, DORLAND'S at 578.

[53] Keppra is the brand name for levetiracetam, a drug used to treat seizures and epilepsy. *Keppra,* DORLAND'S at 978; *levetiracetam*, DORLAND'S at 1031.

[54] There are no records filed documenting when Ms. Galindo developed seizures.

[55] "Silvadene" is the brand name for silver sulfadiazine, which is used as a topical antibacterial cream. *Silvadene*, DORLAND'S at 1717; *silver sulfadiazine*, DORLAND'S at 1718.

[56] Triamcinolone is a steroid used as an anti-inflammatory and an immunosuppressant. *Triamcinolone*, DORLAND'S at 1959.

[57] Ativan is the brand name for lorazepam, a drug with sedative effects used intravenously to control epilepsy and as an antiemetic in cancer chemotherapy. *Ativan*, DORLAND'S at 173; *lorazepam*, DORLAND'S at 1074.

On January 21, 2016, Ms. Galindo presented to Dr. Brenner and Dr. Bowhay, an oncology fellow, for a follow up. Pet. Ex. 11 at 86. She reported mild worsening of left arm weakness, particularly with abduction and grip strength. *Id.* An MRI showed disease progression with an increase of 34% from baseline. *Id*. at 91. TH-302 and Avastin was discontinued. *Id*. She opted to be treated with Avastin and Lomustine;[58] however, she could not be treated with the new regimen at this appointment due to a change in her insurance requiring new prior authorization. *Id*. She was scheduled for another MRI in four weeks. *Id*.

Ms. Galindo returned to Dr. Brenner and Dr. Bowhay on February 18, 2016, for a follow-up. An MRI performed the day before showed that her disease had progressed another 24%. Pet. Ex. 11 at 81. Two weeks before, she had an episode of sudden onset of left leg weakness, fell, and was unable to walk. *Id*. She was taken to the emergency room and diagnosed with a seizure.[59] *Id*. Her dosage of Keppra was increased, and she had not had any further seizure activity since. *Id*. Clinical trial options were discussed. *Id*. at 85-86. Dr. Brenner noted that clinical trial participation was the only remaining option short of hospice. *Id*. at 86. Avastin would be prescribed until Ms. Galindo could be admitted to the clinical trial. *Id*.

On March 3, 2016, Ms. Galindo presented to Ms. Diaz to start treatment on the Phase I trial of KX2-361. Pet. Ex. 11 at 71. She reported that her last seizure had been "1 month ago," but the week before, she was taken to the emergency room due to an episode of hemoptysis; she coughed up a small blood clot upon waking.[60] *Id.* She was administered platelets and released. *Id.* She had not had further episodes of bleeding. *Id*.

On March 10, 2016, Ms. Galindo presented to Dr. Brenner and Dr. Bowhay for follow-up. Pet. Ex. 11 at 65. She had no new symptoms to report since beginning the Phase I trial of KX2-361. *Id.* She was noted to be tolerating treatment well and it was recommended that she continue with treatment as planned. *Id*. at 69-70.

On March 17, 2016, Ms. Galindo presented to Wendy Crabbe, a nurse practitioner for Dr. Kaklamani, for an oncology follow-up. Pet. Ex. 11 at 63. She was feeling well; her left facial droop and left arm and leg weakness were all stable. *Id*. She had not had any new side effects from the new treatment. *Id*.

On March 24, 2016, Ms. Galindo presented to Ms. Diaz for follow-up. Pet. Ex. 11 at 58. She reported increased headaches which were mild and fleeting. *Id*. It was recommended she continue with treatment as planned. *Id*. at 62.

On March 28, 2016, Ms. Galindo presented to Ms. Diaz with increased headaches and vomiting. Pet. Ex. 11 at 53. She had been seen in the ER twice the night before due to uncontrolled

[58] Lomustine is a chemotherapeutic drug used to treat Hodgkin's lymphoma and brain tumors, including malignant glioma. *Lomustine – Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/Gleostine-lomustine-3826 (last visited Mar. 25, 2019).

[59] Records for Ms. Galindo's visit to the emergency room were not filed.

[60] Records of this emergency room visit were not filed.

vomiting and headache. *Id*. She presented around 11:00 pm, and received IV fluids, Zofran,[61] and morphine and was discharged. She returned around 4:00 am and had seizure-like activity while in the ER. *Id*. She received IV fluids, Zofran, morphine, and IV Keppra.[62] *Id*. She was noted to be on the Phase I trial of KX2-361 with no side effects. *Id*. Ms. Diaz discussed Ms. Galindo's case with Dr. Brenner and a conclusion was reached that her symptoms were related to her glioblastoma. She possibly had increased cerebral edema since discontinuing Avastin.[63] *Id*. at 57. Ms. Diaz recommended treatment with IV fluids, Decadron,[64] and Avastin. *Id*.

A brain MRI performed on March 31, 2016, compared to a previous MRI on February 17, 2016, revealed significant progression, "predominantly T2 hyperintense lesions with the bilateral cerebral hemispheres, greater on the right (compatible with patient's known diagnosis of glioblastoma)." Pet. Ex. 11 at 51. Ms. Galindo was "[a]dvised that she has significant swelling and disease progression and limited treatment options." *Id*.

On April 7, 2016, Ms. Galindo presented to Dr. Crownover at UT San Antonio. Dr. Crownover noted that she had been on a Phase I trial of KX2-361 but recently had progression and was referred to radiation oncology. Pet. Ex. 11 at 47. She had headaches the week prior which resolved with use of Decadron. *Id*. During the appointment, she reported feeling relatively well. *Id*. She was noted to be a candidate for re-irradiation as a "purely palliative maneuver." *Id*. She reported mild worsening of left arm weakness over the past month, and constipation which was controlled with stool softeners. *Id*. at 49. She was on Keppra for focal seizures. *Id*. at 51.

On April 15, 2016, Ms. Galindo presented to Dr. Crownover at UT San Antonio for palliative treatment. Pet. Ex. 11 at 4. She received palliative radiation treatments on April 18 and 20, 2016. Pet. Ex. 11 at 6-15.

Ms. Galindo passed away on April 22, 2016 at Hill Country Memorial Hospital.[65] Her cause of death was listed as respiratory failure secondary to cerebral herniation[66] and glioblastoma multiforme. ECF No. 34 at 1. An autopsy was not performed. *Id*.

II. Discussion

A. Legal Standard

The Vaccine Act provides petitioners with two avenues to receive compensation for their injuries resulting from vaccines or their administration. First, a petitioner may demonstrate that he

[61] Zofran is the brand name for ondansetron HCl. *Zofran*, DORLAND'S at 2092.

[62] Records of these emergency room visits were not filed.

[63] The records do not clearly state when Ms. Galindo stopped taking Avastin, but it appears that Avastin was discontinued when she began the clinical trial for KX2-361. *See* Pet. Ex. 11 at 86.

[64] Decadron is the brand name for dexamethasone. *Decadron*, DORLAND'S at 474.

[65] No records were filed documenting this hospitalization.

[66] Cerebral herniation occurs when brain matter protrudes through the cranium. *Cerebral hernia*, DORLAND'S at 848.

or she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Alternatively, where the alleged injury is not listed on the Vaccine Injury Table, a petitioner may bring an "off-Table" claim. § 11(c)(1)(C)(ii). An "off-Table" claim requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 11(c)(1)(C)(ii)(II). Initially, a petitioner must provide evidence that he or she suffered, or continues to suffer, from a definitive injury. *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1346 (Fed. Cir. 2010). A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the alleged injury; showing that the vaccination was a "substantial factor" and a "but for" cause of the injury is sufficient for recovery. *See Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).[67]

To prove causation, petitioners must satisfy the three-pronged test established in *Althen v. Sec'y of Health & Human Servs*., 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioners show by preponderant evidence that a vaccination petitioner received caused his or her injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id*. at 1278. Together, these prongs must show "that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Stone v. Sec'y of Health & Human Servs*., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (quoting *Shyface*, 165 F.3d at 1352-53). Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." *Knudsen v. Sec'y of Health & Human Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

Each of the *Althen* prongs requires a different showing. Under the first *Althen* prong, petitioner must provide a "reputable medical theory" demonstrating that the vaccine received can cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citation omitted). To satisfy this prong, petitioner's "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (quoting *Althen*, 418 F.3d at 1278). This theory need only be "legally probable, not medically or scientifically certain." *Id*. at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find

[67] The Vaccine Act also requires petitioners to show by preponderant evidence the vaccine suffered from the "residual effects or complications" of the alleged vaccine-related injury for more than six months, died from the alleged vaccine-related injury, or required inpatient hospitalization and surgical intervention as a result of the alleged vaccine-related injury. § 11(c)(1)(D). It is undisputed that this requirement is satisfied in this case.

support for their theories in medical literature." *LaLonde v. Secretary of Health & Human Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014).

The second *Althen* prong requires proof of a "logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). Even if the vaccination can cause the injury, petitioner must show "that it did so in [this] particular case." *Hodges v. Sec'y of Health & Human Servs*., 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). "A reputable medical or scientific explanation must support this logical sequence of cause and effect," *id*. at 961 (citation omitted), and "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury," *Paluck v. Sec'y of Health & Human Servs*., 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375).

The third *Althen* prong requires that petitioner establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *De Bazan v. Sec'y of Health & Human Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id*. However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id*.; *see also Locane v. Sec'y of Health & Human Servs*., 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

A petitioner may also be eligible for compensation if he or she had a preexisting condition which was significantly aggravated by a vaccine. *See* § 11(c)(1)(C). In considering a significant aggravation claim for an on-Table injury, the Federal Circuit placed the most significant on whether petitioner's symptoms began within the time period proscribed. *Whitecotton v. Sec'y of Health & Human Servs*., 81 F.3d 1099, 1107 (Fed. Cir. 1996) ("Instead of asking whether the person's symptoms would have occurred absent the vaccine, our test hoves close to the statutory mandate, and relieves a petitioner of the burden of proving causation if she can show that the first symptom or manifestation of the significant aggravation of her condition occurred within the table time period provided in the statute.")

For a significant aggravation claim for an off-Table injury, the petitioner's burden is raised, requiring petitioner to show, by preponderant evidence, proof of

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason

> for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving ex rel. Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135, 144 (2009). The fourth, fifth, and sixth factors are derived from *Althen* prongs one, two, and three, respectively. *Id*. The Federal Circuit has agreed with this approach. *See W.C. v. Sec'y of Health & Human Servs*., 704 F.3d 1352, 1357 (Fed. Cir. 2013) ("We hold that the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims.") Due to the requirement to prove causation, one special master has recommended evaluating "the last three *Loving* factors first." *Hennessey v. Sec'y of Health & Human Servs*., No. 01–190V, 2009 WL 1709053, at *42 (Fed. Cl. Spec. Mstr. May 29, 2009), *motion for review denied*, 41 Fed. Cl. 126 (2010).

However, the third *Loving* factor, determining whether the person suffered a "significant aggravation" of his or her condition, leads to the question of what constitutes a significant aggravation. Based on the legislative history and the language of the statute, it appears that Congress intended for a "significant aggravation" of a condition to present rather dramatically. *See* H.R. Rep. 908, 99th Cong.2d Sess. 1, reprinted in 1986 USCCAN 6287, 6356 ("This [significant aggravation] provision does not include compensation for conditions which might legitimately be described as preexisting (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), *but is meant to encompass serious deterioration* (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis" (emphasis added)); *see also* 42 U.S.C. § 300aa-33(4) ("The term "significant aggravation" means any change for the worse in a preexisting condition which results in *markedly greater* disability, pain, or illness accompanied by *substantial deterioration* of health" (emphases added)).

Once a petitioner has established that his or her condition worsened post-vaccination, the special master must determine "whether the change for the worse in [petitioner's] clinical presentation was aggravation or a natural progression" of the preexisting condition. *Hennessey*, 2009 WL 1709053 at *42. In doing so, special masters have relied on evidence supporting the "typical" clinical course of the petitioner's condition. *See, e.g., Locane*, 685 F. 3d at 1381-82 (Special master's determination that petitioner's Crohn's disease was not significantly aggravated by her hepatitis B vaccinations where her disease flare-ups after her first and third vaccinations were typical of frequent flares in adolescents' expected course of Crohn's disease was reasonable); *Faoro v. Sec'y of Health & Human Servs*., No. 10-704V, 2016 WL 675491, at *27 (Fed. Cl. Spec. Mstr. Jan. 29, 2016), *mot. for review denied*, 128 Fed. Cl. 61 (Fed. Cl. Apr. 11, 2016) (finding that "the vaccinations would not have changed her clinical course and thus, the vaccinations did not significantly aggravate her preexisting condition").

Finally, although this decision discusses much but not all of the evidence filed in detail, the undersigned reviewed and considered all of the evidence filed in this matter, including but not limited to the medical records and literature that was filed. *See Moriarty ex rel. Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

B. Overview of Glioblastoma

Glioblastoma, or glioblastoma multiforme, is the most common brain and central nervous system malignancy, accounting for 45.2% of malignant primary brain and CNS tumors. Pet. Ex. 14 at 533 (Tab 39[68]). The World Health Organization has designated glioblastoma as grade IV, which is assigned to malignant tumors "typically associated with rapid pre- and postoperative disease evolution and a fatal outcome." Pet. Ex. 14 at 26 (Tab 1[69]). It often manifests rapidly after a short clinical history, and the majority of those affected die within a year of diagnosis. Pet. Ex. 14 at 123 (Tab 7[70]); Pet. Ex. 14 at 28 (Tab 1). Of patients who respond to first-line treatment, "virtually all" have a period of "progression-free survival" for 7 to 10 months before experiencing a recurrence. Resp. Ex. A-1 at 5. Long-term survivors are patients who survive at least 2.5 years post-diagnosis. Pet. Ex. 14 at 530 (Tab 38[71]). Less than 5% of patients survive five years post-diagnosis. Pet. Ex. 14 at 50 (Tab 2[72]); *see also* Resp. Ex. A-1 at 2[73] (Noting that the five-year survival rate for people with glioblastoma is 4.7%).

The cause of glioblastoma remains obscure; however, oncogenes and tumor suppression genes are known to be involved in the evolution of glioblastoma, and certain gene mutations have been associated with development of glioblastoma. Pet. Ex. 14 at 274 (Tab 25[74]); Pet. Ex. 14 at 123 (Tab 7); Pet. Ex. 14 at 115 (Tab 6[75]). Prior treatment with therapeutic radiation has been identified as a risk factor for glioblastoma. *See* Pet. Ex. 14 at 253 (Tab 22[76]); Pet. Ex. 14 at 255 (Tab 23[77]).

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[68] Jigisha P. Thakkar et al., *Epidemiologic and Molecular Prognostic Review of Glioblastoma*, 23 CANCER EPIDEMIOL BIOMARK PREV 10: 1985-96 (2014).

[69] David N. Louis et al., *The 2007 WHO Classification of Tumours of the Central Nervous System*, 114 ACTA NEUROPATHOL 97-109 (2007)

[70] Hiroko Ohgaki et al., *Genetics Pathways to Glioblastoma: A Population-Based Study*, 64 CANCER RES 6892-99 (2004).

[71] N.R. Smoll et al., *Long-Term Survival of Patients with Glioblastoma Multiforme (GBM)*, 20 J CLIN NEUROSCI 5: 670-75 (2013).

[72] Quinn T. Ostrom et al., *CBTRUS Statistical Report: Primary Brain and Central Nervous System Tumors Diagnosed in the United States in 2006-2010*, 15 NEURO-ONCOL ii1-ii56 (2013).

[73] Antonio Omuro & Lisa M. DeAngelis, *Glioblastoma and Other Malignant Gliomas: A Clinical Review*, 310 JAMA 17: 1842-50 (2013).

[74] Margaret Wrensch et al., *Variants in the CDKN2B and RTEL1 Regions Are Associated with High Grade Glioma Susceptibility*, 41 NAT GENET 8: 905-08 (2009).

[75] Paul Kleihues & Hiroko Ohgaki, *Phenotype vs. Genotype in the Evolution of Astrocytic Brain Tumors*, 28 TOXICOL PATHOL 1: 164-70 (2000).

[76] L.C. Hodges et al., *Prevalence of Glioblastoma Multiforme in Subjections with Prior Therapeutic Radiation*, 24 J NEUROSCI NURS 2: 79-83 (1992).

[77] Judith A. Schwartzbaum et al., *An International Case-Control Study of Interleukin-4Rα, Interleukin-13, and Cyclooxygenase-2 Polymorphisms and Glioblastoma Risk*, 16 CANCER EPIDEMIOL BIOMARK PREV 11: 2448-54 (2007).

Multiple studies have found that patients who were treated with post-operative radiation therapy with concurrent temozolomide had an increase in survival time. *See* Pet. Ex. 14 at 91 (Tab 3[78]) (Study finding that these patients had a median survival of 15 months and a two-year relative survival of 26%); Pet. Ex. 14 at 110 (Tab 5[79]) (Study finding that patients with radiation alone had a median survival time of 12 months, while patients who received radiation and temozolomide had a median survival time of 14.6 months); Pet. Ex. 14 at 190 (Study finding that these patients had a median survival rate of 16 months) (Tab 12[80]).

C. Expert Reports

1. Petitioner's Expert, Dr. Mark Levin

Petitioner filed three reports from his expert, Dr. Mark Levin. Dr. Levin earned his medical degree from SUNY-Downstate Medical College and completed residencies at New York Downtown Hospital, Hahnemann University Medical Center, and Long Island Jewish Hillside Hospital Medical Center. ECF No. 19-2 at 1. He is board certified in internal medicine, hematology, and oncology. *Id*. From 2005 to 2009, he was an attending physician at the University of Medicine and Dentistry of New Jersey at Newark. *Id*. at 2. While in that position, Dr. Levin "was responsible for diagnosis and treating the majority of brain cancer patients presenting to that institution…." ECF No. 19 at 1.

Dr. Levin's opinion is based on a theory that the HPV vaccine contains virus-like particles ("VLPs") which cross the blood-brain barrier and are capable of "acting as a promoter that accelerated [the] growth and virulence" of glioblastoma. ECF No. 19 at 3; Pet. Ex. 12 at 2; Pet. Ex. 14 at 10.

According to Dr. Levin, HPV vaccine contains VLPs produced by HPV L1, the major capsid protein in the HPV vaccine. Pet. Ex. 14 at 6; *see also* Resp. Ex. A-2 at 7-8.[81] "[T]here is evidence that components (including HPV-16L1) of the HPV vaccine…can cross the blood brain barrier." Pet. Ex. 14 at 11. He based this theory on one article authored by Tomljenovic and Shaw[82] which concluded that HPV-16L1 VLPs could cross the blood-brain barrier and cause cerebral vasculitis.[83] Pet. Ex. 14 at 6-11; *see also* Pet. Ex. 8 at 9. The article stated that brain tissue

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[78] Matthew Koshy et al., *Improved Survival Time Trends for Glioblastoma Using the SEER 17 Population-Based Registries*, 107 J NEUROONCOL 1: 207-12 (2012).

[79] Roger Stupp et al., *Radiotherapy plus Concomitant and Adjuvant Temozolomide for Glioblastoma*, 352 N ENGL J MED 987-96 (2005).

[80] K. Robin Yabroff et al., *Patterns of Care and Survival for Patients with Glioblastoma Multiforme Diagnosed During 2006*, 14 NEUROONCOL 3: 351-59 (2012).

[81] Lauri E. Markowitz et al., *Human Papillomavirus Vaccination: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 63 MMWR 1-30 (2014).

[82] His expert report repeatedly cites to Ref. 39, which is an article on glioblastoma; it appears that he intended to reference the article filed as Pet. Ex. 8, which is a case report on two deaths after HPV vaccination.

[83] Vasculitis encompasses a family of disorders characterized by inflammation of the blood vessels, which

specimens from two patients who had received HPV vaccinations showed that HPV-16L1 antibodies bonded to the walls of cerebral blood vessels. Pet. Ex. 14 at 5-6; Pet. Ex. 8 at 3. According to Dr. Levin, this finding "demonstrates that vaccine-derived immune complexes are capable of penetrating the blood-brain barrier." Pet. Ex. 14 at 6; Pet. Ex. 8 at 3.

Furthermore, Dr. Levin submitted that once the HPV-16L1 VLPs cross the blood-brain barrier, they can activate microglia, "the brain's resident immune cells." Pet. Ex. 14 at 7; Pet. Ex. 8 at 3. Activation of microglia increases "the permeability of the blood-brain barrier to other inflammatory factors and to trafficking lymphocytes." *Id*. Dr. Levin suggested that antibodies to the HPV-16L1 VLPs also cross the blood-brain barrier and, via molecular mimicry, attack cerebral blood vessels where the VLPs have deposited, thereby causing cerebral vasculitis. Pet. Ex. 14 at 9; Pet. Ex. 8 at 4-5. Dr. Levin concluded, "There is significant literature that shows that [HPV] can cross the brain blood barrier and several publications that implicate it in causation or progression of brain tumors, including glioblastoma." ECF No. 19 at 2. Dr. Levin did not cite to any references in support of this statement. Dr. Levin did not explain how his theory that HPV VLPs causing cerebral vasculitis could cause, contribute or transition into the development of brain cancer and specifically glioblastoma. He did not explain how petitioner, who was not diagnosed with vasculitis, developed glioblastoma from HPV VLPs. The literature cited in Dr. Levin's report was never filed with the Court.

2. Respondent's Expert, Dr. Joan Gill

Respondent filed two reports from his expert, Dr. Joan Gill. Dr. Gill earned her medical degree at the Medical College of Wisconsin; she completed her residency in pediatrics at Milwaukee Children's Hospital and a fellowship in pediatric hematology and oncology at the Medical College of Wisconsin's Blood Center of Southeastern Wisconsin. Resp. Ex. B at 1-2. She has been on the faculty of the Medical College of Wisconsin since 1982 and is currently a Professor of Pediatrics, Medicine, and Epidemiology & Population Genetics. *Id*. at 2. She directed the Comprehensive Center for Bleeding Disorders for over 30 years and is board certified in pediatric hematology/oncology and pediatrics. Resp. Ex. A at 1.

Dr. Gill opined that there is no evidence that HPV vaccine causes autoimmune disease or glioblastoma. Resp. Ex. A at 2. She stated that there are no case reports of glioblastoma associated with the HPV vaccine. *Id*. Dr. Gill cited two large population-based studies of women who received HPV vaccinations; neither study found an association between the HPV vaccine and

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restrict blood flow and damages vital organs and tissues. Central nervous system ("CNS") vasculitis is a chronic disease involving the blood vessels that supply the brain and spinal cord. Symptoms of CNS vasculitis include severe headache, stroke, swelling of the brain ("encephalopathy"), forgetfulness, confusion, muscle weakness or paralysis, difficulty with coordination, vision problems, and seizures. The cause of CNS vasculitis has not yet been determined; it is classified as an autoimmune disease but environmental factors, such as infection, and genetic factors are also thought to be involved. CNS vasculitis is typically treated with a high-dose steroid, such as prednisone. *Central Nervous System Vasculitis*, VASCULITIS FOUNDATION, https://www.vasculitisfoundation.org/education/forms/central-nervous-system/#1545061030387-cada6e45-b35f (last visited Apr. 10, 2019).

autoimmune events. *See* Resp. Ex. A-4 at 1;[84] Resp. Ex. A-5 at 1.[85] Moreover, "[t]here were no reports of central nervous system malignancies or glioblastomas." Resp. Ex. A at 3; Resp. Ex. C at 1. In Dr. Gill's opinion, Ms. Galindo's glioblastoma "was the result of incidental glial mutations and her recurrence was consistent with the natural course history of the inevitably progressive nature of glioblastoma." Resp. Ex. A at 3; Resp. Ex. C at 2.

D. Analysis of *Althen* and *Loving* Factors

Petitioner is unable to sustain his burden of proving causation under the three prongs of *Althen* or significant aggravation under the six-factor test established in *Loving*, 86 Fed. Cl. at 144.

1. *Althen* Prong 1/*Loving* Factor 4: Petitioner Failed to Advance a Medical Theory

Because petitioner is required to present a plausible medical theory demonstrating how the HPV vaccine could cause or significantly aggravate glioblastoma, it is logical to evaluate the last three factors of *Loving*, which are also the three prongs of *Althen*, first. *See Hennessey*, 2009 WL 1709053, at *42.

Dr. Levin offered a theory, based on the Tomljenovic and Shaw study submitted as Pet. Ex. 8, that HPV VLPs can cross the blood-brain barrier and, through molecular mimicry, induce the immune system into attacking similar self-antigens contained in cerebral blood vessels, thereby causing cerebral vasculitis. Dr. Levin did not provide any evidence to suggest that cerebral vasculitis could cause, develop into, or significantly aggravate glioblastoma, or explain how HPV VLPs could cause or significantly aggravate glioblastoma.

Dr. Gill disagreed with Dr. Levin on the significance of the Tomljenovic study, pointing out that, of the two patients studied, the first patient's autopsy showed "no evidence of inflammatory changes or neuronal loss; and the second patient showed no evidence of inflammatory processes or microglial reactions in the patient's brain…." Resp. Ex. A at 2, citing Pet. Ex. 8 at 2. Dr. Gill further pointed out that HPV VLPs were found only in the cerebral blood vessels "and not in the neuronal tissues; therefore, there was no evidence that the HPV proteins crossed the blood brain barrier to induce vasculitis." Resp. Ex. A at 2. Additionally, Dr. Gill noted neither of the patients in the study had glioblastoma. *Id.*

Essentially, Dr. Levin's theory relies solely on one study of two patients, neither of whom were diagnosed with glioblastoma or any cancer of the brain. The Tomljenovic study is a case report, which carries "limited weight on the issue of causation." *Bast v. Sec'y of Health & Human Servs*., 2012 WL 6858040, at *39 n.104 (Fed. Cl. Spec. Mstr. Dec. 20, 2012), *mot. for rev. denied sub nom., [M.S.B.] by Bast v. Sec'y of Health & Human Servs*., 117 Fed. Cl. 2014 (2014), *appeal dismissed sub nom., M.S.B. ex rel. Bast v. Sec'y of Health & Human Servs*., 579 Fed. Appx. 1001 (Fed. Cir. 2014); *see also Shepperson v. Sec'y of Health & Human Servs*., No. 05-1064V, 2008

[84] C. Chao et al., *Surveillance of Autoimmune Conditions Following Routine Use of Quadrivalent Human Papillomavirus Vaccine*, 271 J INTERN MED 193-203 (2012).

[85] Tara Harris et al., *Adverse Events Following Immunization in Ontario's Female School-Based HPV Program*, 32 VACCINE 1061-66 (2014).

WL 2156748, at *11 (Fed. Cl. Spec. Mstr. Apr. 30, 2008) (noting that a single case report was not "sufficiently probative to begin the evidentiary climb to a preponderance"). Dr. Levin did not file any other articles to support his theory that HPV VLPs can cause cerebral vasculitis, glioblastoma, or how cerebral vasculitis could become glioblastoma or is in any way related to glioblastoma. Moreover, the Tomljenovic study offers no support for the notion that cerebral vasculitis could in turn cause or evolve into glioblastoma; it does not discuss glioblastoma at all. Dr. Gill stated that there is no literature in which the HPV vaccine is associated with glioblastoma. Though he did not discuss any of these articles in his reports, Dr. Levin included a list of articles that were never filed with the Court. *See* ECF No. 19 at 4-5; Pet. Ex. 12 at 3-4.

In short, Dr. Levin has not presented a "reputable medical or scientific explanation" by which the HPV vaccine could cause glioblastoma or trigger a recurrence of glioblastoma. Accordingly, petitioner has failed to satisfy the first prong of *Althen* and the fourth factor of *Loving*.

2. *Althen* Prong 2/*Loving* Factor 5: Lack of Logical Connection

Even if petitioner had been able to show that the HPV vaccine could cause or significantly aggravate glioblastoma, he did not provide preponderant evidence that it did so in Ms. Galindo's case.

Dr. Levin's theory that HPV vaccine could cause cerebral vasculitis was based upon autopsy findings of HPV-16L1 VLP antibodies in cerebral blood vessels of two individuals in one study as set forth above. There is no evidence in the record to support that Ms. Galindo had cerebral vasculitis, or that the HPV-16L1 VLPs had crossed her blood-brain barrier. Dr. Gill pointed out that Ms. Galindo did not have clinical or MRI evidence of cerebral vasculitis. Resp. Ex. A at 3. Furthermore, because an autopsy was not done on Ms. Galindo, there are no post-mortem findings indicating that she suffered from an autoimmune vasculitis. *See* ECF No. 34 at 1.

Dr. Levin relied on "the absence of other causative factors" to explain how Ms. Galindo's third HPV vaccination resulted in her recurrence of glioblastoma. He noted that she "was not exposed to any type of external factors that could explain the onset of Glioblastoma," and did not fit the statistical profile of the common glioblastoma patient. ECF No. 19 at 3, 4; Pet. Ex. 12 at 3; Pet. Ex. 14 at 10-11. He concluded that, prior to receiving the third HPV vaccination, Ms. Galindo was "cured" of glioblastoma writing that Ms. Galindo was treated for glioblastoma, which "rendered her cancer free." ECF No. 19 at 2; Pet. Ex. 12 at 2; Pet. Ex. 14 at 1. He repeated this sentiment, stating that she "was in complete remission." ECF No. 19 at 4; Pet. Ex. 12 at 3; Pet. Ex. 14 at 11.

Dr. Gill submitted that the concept of "complete remission" for glioblastoma patients is factually incorrect; she explained that even when undetectable by testing, cancer cells in glioblastoma are still present Resp. Ex. A at 2. Moreover, she pointed out that none of Ms. Galindo's oncologists used the term "cancer free." *Id.* In Dr. Gill opined that Ms. Galindo's "recurrence was consistent with the natural course history of the inevitably progressive nature of glioblastoma." *Id.* at 3; Resp. Ex. C at 2. To support this opinion, Dr. Gill cited to Omuro et al., which noted that "virtually all glioblastoma patients experience disease progression after a median [progression-free survival] of 7 to 10 months." Resp. Ex. A-1 at 5.

Dr. Gill's opinion is supported by the medical records, which indicate that Ms. Galindo was still receiving maintenance chemotherapy in December of 2012, approximately one month before she received her third HPV vaccination on January 21, 2013. *See* Pet. Ex. 11 at 47 (Noting that Ms. Galindo continued taking Temodar, irinotecan, and bevacizumab, which are all chemotherapeutic drugs, through December 2012).

In contrast, Dr. Levin does not seem to rely on the medical records in this matter at all, but rather on the facts and timeline as contained in the Petition, which are inconsistent with the medical records. Although the medical records are spotty and incomplete, none of the records filed indicate that Ms. Galindo was ever determined to be "cancer free," as stated by Dr. Levin in all three of his reports. Moreover, patients with glioblastoma are essentially never "cancer free," as the disease is characterized as a Grade IV cancer with inevitable progression and recurrence until the patient succumbs. *See* Pet. Ex. 14, Tabs 1, 2, 3, 5, 7, 12, 38; *see also* Resp. Ex. A-1 at 2, 5.

"When evaluating the reliability of an expert's opinion, it is important to ascertain whether the information on which the doctor is relying is accurate because inaccuracies in the expert's factual assumptions compromise the reliability of the view offered." *Dillon v. Sec'y of Health & Human Servs*., No. 10-850V, 2013 WL 3745900, at *14 (Fed. Cl. Spec. Mstr. June 25, 2013) (citing *Perreira v. Sec'y of Health & Human Servs*., 33 F. 3d 1375, 1377 n.6 (Fed. Cir. 1994) ("An expert opinion is no better than the soundness of the reasons supporting it.")). Dr. Levin's reliance on inaccurate facts and an inaccurate timeline rather than the facts and dates as contained in the medical records negatively impacts the reliability and soundness of his opinion, and as such, it carries little weight.

Furthermore, Dr. Levin appears to rely on *post-hoc, ergo propter hoc* reasoning to connect Ms. Galindo's recurrence of glioblastoma to her third HPV vaccination. This type of reasoning has been heavily disfavored by courts generally, and by the Vaccine Program specifically. *See, e.g., U.S. Steel Group v. United States*, 96 F. 3d 1352, 1358 (Fed Cir. 1996) ("But to claim that the temporal link between these events *proves* that they are casually related is simply to repeat the ancient fallacy: *post hoc ergo propter hoc*") (emphasis in original); *Fricano v. United States*, 22 Cl. Ct. 796, 800 (1991) ("*[P]ost hoc ergo propter hoc*…is regarded as neither good logic nor good law") (emphasis in original); *Doe/34 v. Sec'y of Health & Human Servs*., 2009 WL 1955140, at *10 (Fed. Cl. Spec. Mstr. Mar. 4, 2009); *Pafford v. Sec'y of Health & Human Servs*., No. 01-0165V, 2004 WL 1717359, at *9 (Fed. Cl. Spec. Mstr. July 16, 2004), *mot. for rev. denied*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F. 3d 1352 (Fed. Cir. 2006). Dr. Levin provided no evidence from Ms. Galindo's medical records to support his theory other than her lack of risk factors for glioblastoma. This is insufficient to support a logical sequence of cause and effect connecting Ms. Galindo's development of or recurrence of glioblastoma to her third HPV vaccination. Accordingly, petitioner has not satisfied the second prong of *Althen* and the fifth factor of *Loving*.

3. *Althen* Prong 3/*Loving* Factor 6: No Proximate Temporal Relationship

During a status conference on August 11, 2016, Mr. Rosales represented that Ms. Galindo began experiencing symptoms related to her recurrence in September of 2013, approximately 8 months after her third HPV vaccination. This is not supported by Ms. Galindo's medical records. The records submitted document visits to Mid-Texas on August 5, 2013, September of 2013, and

November 1, 2013, none of which showed complaints associated with glioblastoma but rather related to general illness. Pet. Ex. 6 at 1-4. The medical records submitted indicate that Ms. Galindo's recurrence was diagnosed in June of 2015. Pet. Ex. 11 at 4, 47, 86. This places her recurrence approximately 28 months after she received the third HPV vaccination on January 21, 2013. Pet. Ex. 7 at 4.

To satisfy the sixth factor of *Loving*, which requires petitioner show a proximate temporal relationship between Ms. Galindo's third HPV vaccination on January 21, 2013, and her recurrence of glioblastoma 28 months later, petitioner would need to demonstrate an appropriate timeframe for a significant aggravation of glioblastoma following an HPV vaccine. However, since petitioner cannot show that the HPV vaccine can cause or significantly aggravate glioblastoma, petitioner cannot show what a reasonable timeframe for the cause or significant aggravation of glioblastoma following HPV vaccination would be. *Langland v. Sec'y of Health & Human Servs.*, 109 Fed. Cl. 421, 443 (2013) ("[T]o satisfy the 'proximate temporal relationship' prong of the *Althen* test, petitioners must demonstrate, by a preponderance of the evidence, that the onset of symptoms occurred within a time frame for which it is medically acceptable to infer causation-in-fact….With no reputable theory as to how the vaccination could cause the injury, this exercise is not possible.") (citing *De Bazan*, 539 F.3d at 1352).

The statute describes "significant aggravation" as "substantial deterioration" or "markedly greater" illness or disability, neither of which Ms. Galindo experienced following her third HPV Vaccination. *See* 42 U.S.C. § 300aa-33(4). Rather, she presented to her doctors for mild illnesses such as pharyngitis, sinusitis, and bacterial vaginosis before having a recurrence of glioblastoma 28 months after receiving the third HPV vaccine. *See* Pet. Ex. 6 at 1-4; Pet. Ex. 10 at 116-30. The progression of her glioblastoma was in keeping with the progression of the disease.

The facts and timeframe upon which Dr. Levin based his opinions were factually inaccurate and inconsistent with the medical records. All three of his reports state that Ms. Galindo's recurrence occurred "within a year" of her third HPV vaccine. *See* ECF No. 19 at 2; Pet. Ex. 12 at 2; Pet. Ex. 14 at 1. The medical records do not support this, but rather indicate that her third HPV vaccine was received on January 21, 2013 and her recurrence of glioblastoma occurred in June of 2015, two years and four months later. *See* Pet. Ex. 11 at 4, 47, 86. Dr. Levin provided no explanation for how the HPV vaccination could significantly aggravate a preexisting glioblastoma within a year of vaccination, and further failed to provide any explanation for how it resulted in a recurrence 28 months or two years and four months later. Accordingly, Dr. Levin's opinions are unpersuasive, and petitioner has failed to present preponderant evidence to support the third prong of *Althen* and the sixth factor of *Loving*.

4. *Loving* Factor 1: Ms. Galindo's Condition Prior to the 3rd HPV Vaccine

In October of 2011, Ms. Galindo was diagnosed with glioblastoma, a rapidly progressive stage IV brain cancer of unknown origin. *See* Pet. Ex. 5 at 2; Pet. Ex. 7 at 2; Pet. Ex. 11 at 48. She had a craniotomy for partial tumor removal, followed by radiation therapy with concurrent temozolomide. Pet. Ex. 5 at 10; Pet. Ex. 11 at 48. Ms. Galindo continued to take chemotherapeutic medications, including temozolomide, irinotecan, and bevacizumab, through December of 2012. Pet. Ex. 11 at 47.

5. *Loving* Factor 2: Ms. Galindo's Condition Following the 3rd HPV Vaccine

On January 21, 2013, Ms. Galindo received a third HPV vaccination and an intranasal flu vaccine. Pet. Ex. 7 at 4. She subsequently presented to her primary care provider on several occasions for treatment of routine illnesses such as pharyngitis, sinusitis, and stomach issues. *See* Pet. Ex. 6 at 1-4; Pet. Ex. 10 at 116-30. Based on an office note for February 14, 2014, at that point, Ms. Galindo had malignant glioblastoma "with no apparent recurrence." Pet. Ex. 10 at 123.

There are two significant gaps in the medical records, from March 27, 2014, until February 18, 2015, and from February 18, 2015, until January 6, 2016. Based on records that were filed Ms. Galindo's recurrence of glioblastoma was documented as June of 2015.[86] Pet. Ex. 11 at 4, 47. She was treated with chemotherapy and participated in two clinical trials. Pet. Ex. 11 at 57-96. Unfortunately, her disease continued to progress, and she passed away on April 22, 2016. *Id.*; ECF No. 34 at 1.

6. *Loving* Factor 3: Ms. Galindo's Condition Was Not "Significantly Aggravated" by the 3rd HPV Vaccine

Ms. Galindo received her third HPV vaccination on January 21, 2013 and had a recurrence of glioblastoma in June of 2015, 28 months later. She passed away in April of 2016. Her recurrence and subsequent death were too remote in time following her third HPV vaccination and were by definition of glioblastoma the result of the natural progression of her disease. Ms. Galindo was diagnosed with glioblastoma in October of 2011 and experienced a recurrence in June of 2015; at that time, she was considered a "long-term survivor" of glioblastoma, having lived more than 3.5 years post-diagnosis. *See* Pet. Ex. 14 at 530. When she passed away in April of 2016, Ms. Galindo was approximately 4.5 years post-diagnosis of glioblastoma. Given that fewer than 5% of glioblastoma patients survive more than five years after diagnosis, the timing of Ms. Galindo's death was more likely attributable to the natural course of her disease rather than the result of or significant aggravation by the HPV vaccine. *See* Pet. Ex. 14 at 50; Resp. Ex. A-1 at 2. Accordingly, petitioner cannot establish that the HPV vaccine significantly aggravated Ms. Galindo's condition such that it changed her clinical course.

III. Conclusion

This case involves a horrible disease that took the life of an active and beautiful young woman at the start of her adult life. My sympathies go out to petitioner and Ms. Galindo's mother and family for this tragic loss. However, upon careful evaluation of all of the evidence submitted in this matter—including the medical records, expert reports, medical literature, and affidavits—the undersigned concludes that petitioner has not shown by preponderant evidence that he is entitled to compensation under the Vaccine Act. Petitioner has failed to offer sufficient evidence

[86] This was gleaned from the histories contained in medical records from 2016.

showing that the HPV vaccination caused or significantly aggravated Ms. Galindo's glioblastoma. The petition is therefore dismissed.

In the absence of a timely filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this decision.[87]

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master

[87] Pursuant to Vaccine Rule 11(a), if a motion for review is not filed within 30 days after the filing of the special master's, the clerk will enter judgment immediately.